UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Schwarz Pharma, Inc., Schwarz Pharma AG, and Warner-Lambert Company, LLC,

Plaintiffs,

v.

Paddock Laboratories, Inc.,

Defendant.

MEMORANDUM OPINION AND ORDER
Civ. No. 05-832 ADM/JJG

Daniel L. Malone, Esq. and Brian M. Poissant, Esq., Jones Day, New York, NY; and Peter R. Forrest, Esq., Gray, Plant, Mooty, Mooty & Bennett, P.A., Minneapolis, MN, argued on behalf of Plaintiffs.

Neil F. Greenblum, Esq., Michael J. Fink, Esq., and Stephen M. Roylance, Esq., Greenblum & Bernstein, P.L.C., Reston, VA; and Beth L. Steffan, Esq., Kelly & Berens, PA, Minneapolis, MN, argued on behalf of Defendant.

I. INTRODUCTION

On August 30, 2006, oral argument before the undersigned United States District Judge was heard on Paddock Laboratories, Inc.'s ("Paddock") Motion for Summary Judgment of Noninfringment of U.S. Patent No. 4,743,450 ("the '450 patent") [Docket No. 175]. In their Complaint [Docket No. 1], Plaintiffs Schwarz Pharma, Inc. ("SPI"), Schwarz Pharma AG ("SPAG") (SPI and SPAG are collectively "Schwarz Pharma"), and Warner-Lambert Company, LLC ("Warner-Lambert") (all three collectively "Plaintiffs") aver that Paddock's planned commercial manufacture, use, and sale of Moexipril Tablets infringes the '450 patent. For the reasons stated herein, Paddock's Motion for Summary Judgment is granted.

On September 29, 2006, Schwarz Pharma filed Objections [Docket No. 208] to Magistrate Judge Jeanne J. Graham's Order [Docket No. 202] granting Paddock's Motion for

Sanctions for Violation of a Protective Order [Docket No. 163] and ordering Schwarz Pharma to pay reasonable attorney fees and costs incurred by Paddock in bringing its Motion. Schwarz Pharma's Objections are overruled, and Judge Graham's Order is adopted.

II. BACKGROUND

The '450 patent, entitled "Stabilized Compositions," discloses a pharmaceutical composition that combines Angiotensin Converting Enzyme ("ACE") inhibitors with certain stabilizers that prevent degradation, i.e., cyclization, hydrolysis, and discoloration, to create a stable medication for treating hypertension and congestive heart failure. Wiesner Decl. [Docket No. 185] Ex. 1. Warner-Lambert owns the '450 patent. Compl. ¶ 11. Warner-Lambert granted SPAG an exclusive license to manufacture and sell moexipril hydrochloride[1] products under the '450 patent, and SPAG granted an exclusive sublicense to SPI. Id. ¶ 12. SPI sells drug products containing moexipril hydrochloride under the trademark UNIVASC®. Id.

Paddock is a developer, manufacturer, and seller of generic pharmaceutical products. Countercl. [Docket No. 5] ¶ 1. Paddock submitted an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell tablets containing moexipril hydrochloride and magnesium oxide prior to the expiration of the '450 patent.[2] Id. ¶ 38; Compl. ¶¶ 13, 14. Paddock sent a Notification Letter to Plaintiffs, informing them of its ANDA and certification that its product does not infringe any claims of the '450 patent. Countercl. ¶ 40; Compl. ¶ 15. Plaintiffs allege that Paddock's filing of its ANDA

[1] Moexipril hydrochloride is an ACE inhibitor.

[2] The '450 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluation" ("Orange Book") as covering UNIVASC® tablets.

constitutes infringement of one or more of the claims of the '450 patent. Compl. ¶ 16.

Applicants Michael Harris, Gerard Hokanson, Kuchi Murthy, Robert Reisch, and Frank Waldman filed patent application 017,962, entitled "Stabilized Compositions," with the United States Patent and Trademark Office ("PTO") on February 24, 1987. Wiesner Decl. Ex. 3 at S00005. Patent application 017,962 ultimately matured into the '450 patent. Id. The '450 patent as originally filed consisted of 19 claims. Id. at S00028-S00030. Independent claim 1 as originally filed recited:

> A pharmaceutical composition which contains:
> (a) a drug component which comprises an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration,
> (b) a suitable amount of a metal containing stabilizer to inhibit cyclization and discoloration, and
> (c) a suitable amount of a saccharide to inhibit hydrolysis.

Id. at S00028. Dependent claim 2 as originally filed recited: "The composition of Claim 1 wherein (b) contains an alkali or alkaline earth metal salt." Id. Dependent claim 3 as originally filed recited: "The composition of claim 2 wherein (b) contains an alkali or alkaline earth metal carbonate." Id. On October 1, 1987, the patent examiner rejected all 19 claims based on obviousness. Id. at S00034-S00035. The examiner specifically stated: "Claims 1-19 are rejected under 35 U.S.C. [§] 103 as being unpatentable over Veber et al. Veber et al, Examples, teach pharmaceutical compositions containing enalapril and lactose. It is the examiner's opinion that the claimed composition would be obvious in view of Veber et al." Id. at S00035.

In response, an amendment to the patent application was filed on November 23, 1987. Id. at S00037. The amendment asked the examiner to cancel claims 2 and 3, and to amend claims 1, 4, and 18. Id. The amendment essentially folded claims 2 and 3 into claim 1, altering claim 1 to recite "a suitable amount of ~~a metal containing stabilizer~~ an alkali or alkaline earth

metal carbonate . . . ." The amendment also caused originally filed claim 4 to be dependent on claim 1 instead of cancelled claim 3, and asked that in claim 18, the word "salt" be replaced with the word "carbonate." Id.[3] The amendment was supported by approximately one page of remarks, proposed by the applicants' attorney, which informed the examiner that the '450 patent is directed toward stabilized pharmaceutical compositions containing ACE inhibitors and not necessarily toward any specific use for any particular ACE inhibitor. The remarks stated in relevant part:

> Reconsideration is respectfully requested of the rejection of the claims under 35 USC 103 as allegedly being unpatentable over Veber et al. The object and teaching of the Veber patent is a new method of use for known ace inhibitors such as enalapril for treating senile macular degeneration. . . . There is no teaching or suggestion to solve any stability problems by the formulations described in Veber. In fact, there is no mention at all in the entire patent of stability or formulation problems using ACE inhibitors. In contrast, the present invention solves a severe degradation problem of ACE inhibitors which occurs on standing especially at elevated temperatures. . . . Thus, the combination of the two necessary ingredients [an alkali or alkaline earth metal carbonate and a saccharide] demonstrates the patentability of the present invention. This is especially so as now claimed by the above amendment which focuses clearly on the use of an alkali or alkaline earth metal carbonate in combination with a saccharide. Applicant respectfully submits that in view of the above amendment and the above remarks, the Examiner's rejection should be withdrawn.

Id. at S00037-S00038.

On December 30, 1987, a Notice of Allowability was issued, allowing claims 1, and 4-19, as amended. Id. at S00044. An examiner's amendment was also issued, adding the phrase

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[3] Originally filed claim 18 recites:

> A process for stabilizing an ACE inhibitor drug against cyclization which comprises the step of contacting the drug with:
> (a) a suitable amount of an alkali or alkaline earth-metal salt and,
> (b) one or more saccharides.
>
> Id. at S00030.

"a suitable amount" to claim 1(a), so that it now reads "a drug component which comprises a suitable amount of an ACE inhibitor . . . ." Id. at S00045. The '450 patent in its final version, dated May 10, 1988, consists of 17 claims, with claims 1 and 16 as independent claims. Id. at S00005.

On April 18, 2006, the Court issued a Markman order, interpreting certain disputed claim terms of the '450 patent. Order [Docket No. 157]. The Court now turns to Paddock's Motion for Summary Judgment of Noninfringment.

III. DISCUSSION

A. Summary Judgment Standard of Review

Federal Rule of Civil Procedure 56(c) provides that summary judgment shall issue "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); see Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). On a motion for summary judgment, the Court views the evidence in the light most favorable to the nonmoving party. Ludwig v. Anderson, 54 F.3d 465, 470 (8th Cir. 1995). The nonmoving party may not "rest on mere allegations or denials, but must demonstrate on the record the existence of specific facts which create a genuine issue for trial." Krenik v. County of Le Sueur, 47 F.3d 953, 957 (8th Cir. 1995).

B. Prosecution History Estoppel

"A determination of infringement requires a two step analysis. First, the claim must be

properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused [product]." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1565 (Fed. Cir. 1997). "A claim covers an accused [product] if the [product] embodies every limitation of the claim, either literally or by an equivalent." Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1576 (Fed. Cir. 1993). At oral argument, Plaintiffs conceded that Paddock's product does not literally infringe the '450 patent. As a result, the '450 patent is infringed only if Paddock's product is an equivalent, meaning "there is not a substantial difference between the claimed invention and the accused product." Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1218 (Fed. Cir. 1995).

"[P]rosecution history estoppel limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995). Prosecution history estoppel includes both amendment-based estoppel and argument-based estoppel, and is a question of law for the court. Deering Precision Instruments, L.L.C. v. Vector Distribution Sys., Inc., 347 F.3d 1314, 1324 (Fed. Cir. 2003); Ranbaxy Pharms., Inc. v. Apotex, Inc., 350 F.3d 1235, 1240 (Fed. Cir. 2003). "[T]he resolution of factual issues underlying a legal question may properly be decided by the court." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1368 n.3 (Fed. Cir. 2003) ("Festo II").

1. Argument-Based Estoppel

"To invoke argument-based estoppel, the prosecution history must evince a clear and unmistakable surrender of subject matter." Deering Precision Instruments, 347 F.3d at 1326. "Unmistakable assertions made by the applicant to the PTO in support of patentability, whether

or not required to secure allowance of the claim, may operate to preclude the patentee from asserting equivalency." Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1252 (Fed. Cir. 2000). The prosecution history must be examined from an objective standpoint, and the proper inquiry is "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." Id. Additionally,

> [T]estimony as to what a reasonable competitor would conclude from the prosecution history cannot create a genuine issue of material fact so as to bar summary judgment. Such testimony is only a tool, which the judge can use at . . . her discretion, to aid in the legal determination of prosecution history estoppel.

Id. at 1254.

Paddock argues that argument-based prosecution history estoppel bars Plaintiffs from asserting infringement under the doctrine of equivalents. Paddock points to arguments made before the PTO in which the applicants' attorney stated that an alkali or alkaline earth metal carbonate is a necessary ingredient and the claims had been amended to clearly focus on the use of an alkali or alkaline earth metal carbonate. Paddock cites three Federal Circuit cases in support of its argument. See Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241 (Fed. Cir. 2000); Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373 (Fed. Cir. 1999); Tex. Instruments Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165 (Fed. Cir. 1993).

All three cases cited by Paddock are distinguishable from the instant case. Although the patentees in those cases argued to the PTO that a particular aspect of their invention was "critical," "unique," "superior," or "key," they also argued that a potential equivalent to the particular aspect was "not . . . desired," "unworkable," "not . . . easily and readily manufacturable," or a "disadvantage." Bayer, 212 F.3d at 1252-54; Pharmacia, 170 F.3d at 1377-78; Tex. Instruments, 988 F.2d at 1174-75. For example, in Pharmacia, the patentee's

argument that "spray-dried lactose is a critical feature of the present invention" and "lactose which is not spray-dried does not yield a formulation which is easily and readily manufacturable" led the court to conclude that the patentee had surrendered equivalents to its invention that did not contain spray-dried lactose. 170 F.3d at 1377-78. By contrast, in the present case, although the applicants' attorney argued to the PTO that an alkali or alkaline earth metal carbonate was one of the "two necessary ingredients [that] demonstrates the patentability of the present invention" and that the amendment to independent claim 1 was made to "focus[] clearly on the use of an alkali or alkaline earth metal carbonate," he made no arguments with respect to potential equivalents to an alkali or alkaline earth metal carbonate and whether or not they would be less desirable or unworkable. See Wiesner Decl. at S00037-S00038. For example, there is no clear disavowal of magnesium oxide. Furthermore, the purpose of the remarks appears to be directed toward emphasizing the patentability of the '450 patent over the Veber patent because the '450 patent focuses on stabilizing ACE inhibitors, while the Veber patent focuses on using known ACE inhibitors to treat senile macular degeneration. As a result, from the perspective of a reasonable competitor, the arguments before the PTO do not evince a clear and unmistakable surrender of subject matter and argument-based prosecution history estoppel does not apply.

2. Amendment-Based Estoppel

For amendment-based estoppel, "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002) ("Festo I"). Once a court concludes that "a narrowing amendment has been made for a substantial reason related to patentability," a

presumption applies "that the patentee has surrendered all territory between the original claim limitation and the amended claim limitation." Festo II, 344 F.3d at 1367. The patentee may rebut the presumption of total surrender by demonstrating that (1) the alleged equivalent would have been unforeseeable at the time of the narrowing amendment, (2) the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question, or (3) there was "some other reason" suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent. Id. at 1368, citing Festo I, 535 U.S. at 740-41.

a. Presumption of Total Surrender

Paddock argues that the amendment made to the '450 patent was a narrowing amendment made to obtain allowance of the patent after the examiner rejected all of the claims as unpatentable over the prior art. Paddock further argues that as a result, Plaintiffs are deemed to have surrendered coverage for metal containing stabilizers and alkali and alkaline earth metal salts other than alkali and alkaline earth metal carbonates. Paddock points to the arguments made to the examiner as further evidence that the scope of the claims was narrowed, thus giving rise to prosecution history estoppel and an inability to pursue infringement under the doctrine of equivalents.

Plaintiffs respond that the amendment did not presumptively surrender magnesium oxide because the claims of the '450 patent as originally drafted did not encompass magnesium oxide. Accordingly, prosecution history estoppel is inapplicable. Plaintiffs point to the specification to show that the term "metal containing stabilizer" found in original claim 1 means an alkali or alkaline earth metal carbonate, borate, or silicate, and does not include magnesium oxide.

Plaintiffs' argument is not persuasive. The Stabilizer(s) section of the specification states in relevant part:

> The alkaline stabilizers of the invention include the inorganic salts of metals of Groups I and II of the Periodic Table. Thus, salts of alkali and alkaline earth metals are operable. Magnesium, calcium, and sodium are preferred. Magnesium is most preferred. The anionic portion of the salt employe[d] may be any which does not deleteriously affect the stability of the overall formulation. Thus, borates, silicates, and carbonates are contemplated. Carbonates are preferred. Mixtures are operable.

Wiesner Decl. Ex. 1 ('450 patent) at col. 3:30-39. It appears that while borates, silicates, and carbonates are contemplated, they are not exclusive. See Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005) (cautioning courts not to import limitations from the specification into the claims). The specification clearly states that "[t]he anionic portion of the salt employe[d] may be *any* which does not deleteriously affect the stability of the overall formulation. '450 patent at col. 3:35-37 (emphasis added). Here, Plaintiffs' expert conceded that the ordinary and accustomed meaning of an alkali or alkaline earth metal salt would encompass magnesium oxide, and that magnesium oxide is a compound that has anionic portion that does not deleteriously affect the stability of an ACE inhibitor formulation. Pejic Decl. [Docket No. 178] Ex. 2 (Williams Dep.) at 51-52, 98. Thus the claims of the '450 patent as originally drafted encompassed magnesium oxide.

Also, Paddock's argument that the amendment made to the '450 patent was a narrowing amendment is persuasive. The amendment resulted in original independent claim 1 incorporating the limitations of original dependent claims 2 and 3. Plaintiffs' expert agreed that the amendment was a narrowing amendment made to obtain allowance of the patent. Williams Dep. at 82-84. In addition, although the majority of the applicants' attorney's remarks appear to be directed toward demonstrating to the examiner how the '450 patent is distinguishable from

and patentable over the Veber patent—the Veber patent is directed toward a particular use for ACE inhibitors and the '450 patent is directed toward stabilizing ACE inhibitors—the applicants' attorney specifically states that the amendment is in response to the October 1, 1987 Office Action, in which the examiner rejected the '450 patent for obviousness over the prior art. The remarks also point out that "the combination of the two necessary ingredients demonstrates the patentability of the present invention. This is especially so as now claimed by the above amendment which focuses clearly on the use of an alkali or alkaline earth metal carbonate in combination with a saccharide." Wiesner Decl. Ex. 3 at S00038. As a result, the amendment was a narrowing amendment made for a substantial reason related to patentability, and the presumption that the patentee surrendered all territory between the original claim limitation and the amended claim limitation applies.

b. Rebutting the Presumption

i. Foreseeability

The foreseeability test is an "objective inquiry, asking whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment." Festo II, 344 F.3d at 1369. The Federal Circuit has stated that "if the alleged equivalent were known in the prior art in the field of the invention, it certainly should have been foreseeable at the time of the amendment." Id. The foreseeability analysis, while ultimately a matter of law, involves underlying factual issues for which the Court can consider extrinsic evidence including expert testimony. Id.

Paddock argues that Plaintiffs can not rebut the presumption of total surrender because magnesium oxide was known as a stabilizer in the art of pharmaceutical formulation—the field

of the invention of the '450 patent—at the time of the amendment, and therefore was foreseeable as an equivalent. Paddock relies on Glaxo Wellcome Inc. v. Impax Laboratories Inc., 356 F.3d 1348 (Fed. Cir. 2004). In Glaxo, the owner of a patent for a sustained release formulation of the drug bupropion hydrochloride combined with hydroxypropyl methylcellulose ("HPMC"), sued a generic drug manufacturer for infringement based on its ANDA for a sustained release drug combining bupropion hydrochloride with hydroxypropyl cellulose ("HPC"). 356 F.3d at 1350-51. The Federal Circuit upheld the district court's summary judgment determination of noninfringement on the basis of prosecution history estoppel. Id. The court determined that Glaxo had made a narrowing amendment, surrendering other controlled sustained release agents known to act as equivalents for HPMC, and that HPC was a foreseeable sustained release agent at the time of the amendment. Id. at 1352, 1355-56. Although the record showed that at the time of the amendment, only HPMC had been tested specifically with bupropion hydrochloride to achieve sustained release, HPC was known as a sustained release hydrogel-forming polymer in the art of pharmaceutical formulation, as evidenced by the Handbook of Pharmaceutical Excipients, other patents, and an Information Disclosure Statement submitted by Glaxo to the PTO. Id. at 1355-56.

In support of its argument that magnesium oxide was a known stabilizer in the field of pharmaceutical formulation at the time of the amendment on November 11, 1987, Paddock cites to prior art references teaching the use of magnesium oxide as a stabilizer, the knowledge of the inventors of the '450 patent, and the testimony of experts. Paddock avers that the inventors of the '450 patent conducted stability experiments combining magnesium oxide with an ACE inhibitor prior to November 1987. Pejic Decl. Ex. 31-32. Paddock also argues two Japanese

patents, fourteen United States patents, and one Great Britain patent reference magnesium oxide as a stabilizer in the field of pharmaceutical formulation. Pejic Decl. Exs. 12-28.

Plaintiffs respond that Glaxo is distinguishable from the instant case because in Glaxo, the parties did not dispute that HPMC and HPC were known equivalents at the time of the amendment. In this case, Plaintiffs aver two experts have opined that magnesium oxide and magnesium carbonate were not known substitutes or recognized as interchangeable, at the time of the amendment. See Williams Decl. [Docket No. 186] at 6-18; Gokel Decl. [Docket No. 184] at 7-13. But see Dash Decl. [Docket No. 179] at 19-29. Plaintiffs also argue that Paddock's expert witness, Dr. Dash, presents a logically inconsistent opinion that while magnesium oxide was foreseeable at the time of the amendment, it is not an equivalent to magnesium carbonate today. Further, Plaintiffs argue that Paddock's references to other patents are not instructive, as none of the other patents concern ACE inhibitors, and none of the other patents mention cyclization. Plaintiffs also argue that what the '450 patent inventors understood is irrelevant to what a person of ordinary skill in the art understood. Further, the inventors' experiments do not support Paddock's contentions.

The Court finds that an analysis of the entire record, including Paddock's prior art references and the testimony of the experts, reveals that magnesium oxide was a known stabilizer in the field of pharmaceutical formulation at the time of the amendment of the '450 patent. In Glaxo, the court found that although only HPMC had been tested specifically with bupropion hydrochloride to achieve sustained release, HPC was known as a sustained release hydrogel-forming polymer in the art of pharmaceutical formulation, and as a result, was foreseeable as an equivalent to HPMC. Id. at 1355-56. Similarly, in this case, although Paddock's prior art

references do not concern ACE inhibitors, they still show that magnesium oxide was known as a stabilizer in the field of pharmaceutical formulation, and as a result, it was foreseeable to one of ordinary skill in the art as a potential equivalent to magnesium carbonate at the time of the amendment.[4] Because magnesium oxide was foreseeable, the Festo presumption is not rebutted and summary judgment on the basis of prosecution history estoppel is granted.

ii. Tangential Relation

The "tangential relation" test requires a patentee to establish that the objectively apparent reason for the narrowing amendment, discernible from the prosecution history record, was not directly relevant to the alleged equivalent. Festo II, 344 F.3d at 1369. In its opening memorandum, Paddock argues that Plaintiffs can not satisfy the "tangential relation" test because the narrowing amendment was made to overcome the examiner's prior art rejection, as is evident from the applicants' attorney's argument to the examiner that the patentability of the invention is apparent "as now claimed by the above amendment which focuses clearly on the use of an alkali or alkaline earth metal carbonate in combination with a saccharide." Wiesner Decl. Ex. 3 at S00038. Plaintiffs respond that they can satisfy the "tangential relation" test because the amendment had nothing to do with the examiner's rejection, and the prosecution history shows that the applicants asked the examiner to reconsider his obviousness rejection since the Veber patent concerns the use of ACE inhibitors in the treatment of eye disease and the '450 patent

[4] The Court finds the arguments concerning what the inventors knew or did not know about magnesium oxide as a stabilizer to be irrelevant to determining what a person of ordinary skill in the art at the time of the amendment knew. See Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985). However, it is of interest that inventor Frank Waldman conducted stability experiments using magnesium oxide, Quinapril (an ACE inhibitor), and lactose on July 15, 1987, prior to the amendment of the '450 patent. Pejic Decl. Exs. 11 (Waldman Dep.) at 40-42, 31 at 55.

concerns stabilizing ACE inhibitor formulations. In its reply memorandum, Paddock states that even if the amendment was not made to overcome the examiner's rejection, Plaintiffs have still not set forth a reason for the narrowing amendment and therefore can not argue that the rationale behind the amendment bore no more than a tangential relationship to magnesium oxide. See Festo II, 344 F.3d at 1371-72.

As is discussed above, the amendment was a narrowing amendment made to obtain allowance of the patent. The applicants intended to make it clear to the examiner that the '450 patent was patentable over the Veber patent—even though the '450 patent disclosed a pharmaceutical composition that contained an ACE inhibitor and a saccharide, as did the Veber patent, it also disclosed some type of metal containing stabilizer and was directed specifically toward stabilizing all types of ACE inhibitors, while the Veber patent was only directed toward using ACE inhibitors to treat senile macular degeneration. Although there is no evidence that the applicants had magnesium oxide in mind when they made the amendment, the fact remains that the amendment was a narrowing amendment which had the effect of potentially surrendering all territory between the original claim limitation and the amended claim limitation, including magnesium oxide. As a result, the Plaintiffs can not establish that the objectively apparent reason for the narrowing amendment was not directly relevant to the alleged equivalent. Also, even if the amendment was not made to overcome the examiner's prior art rejection, the Plaintiffs have not provided an alternative reason for the amendment, as they are required to do. See Festo II, 344 F.3d at 1371-72. Plaintiffs can not rebut the Festo presumption by satisfying the tangential relation test.

C. Objections to Magistrate Judge Jeanne J. Graham's Order

On September 15, 2006, Magistrate Judge Jeanne J. Graham issued an Order granting Paddock's Motion for Sanctions for Violation of a Protective Order and ordering Schwarz Pharma to pay reasonable attorney fees and costs incurred by Paddock in bringing its Motion. Schwarz Pharma has filed Objections to Judge Graham's Order, arguing that their violation of the protective order was merely inadvertent or technical and Paddock has suffered no harm. As a result, they argue Schwarz Pharma should not have to pay attorney fees and costs. Paddock responds that it was harmed by Schwarz Pharma's violation of the protective order, and as a remedy, the Court should strike the portions of Plaintiffs' expert reports that rely on PharmaForm's testing and preclude Plaintiffs from introducing any testimony or evidence relating to the tests.

In reviewing objections to a Magistrate Judge's order, the District Judge "shall consider such objections and shall modify or set aside any portion of the Magistrate Judge's order found to be clearly erroneous or contrary to law." D. Minn. LR 72.2(a); see also 28 U.S.C. § 636(b)(1)(A). "Civil contempt may be employed either to coerce the defendant into compliance with a court order or to compensate the complainant for losses sustained, or both." Chicago Truck Drivers v. Brotherhood Labor Leasing, 207 F.3d 500, 504 (8th Cir. 2000). In this case, as Judge Graham found, Schwarz Pharma concedes it violated the protective order, and Paddock's Motion has merit. As a result, an award of Paddock's reasonable attorney fees and costs in connection with bringing the Motion is an appropriate remedy, and Judge Graham's holding was not clearly erroneous or contrary to law. See Kehm v. Proctor & Gamble Mfg. Co., 724 F.3d 630, 630-31 (8th Cir. 1984) (holding award of attorney fees in connection with contempt

proceedings appropriate where party disclosed documents subject to a protective order). Further, in light of the Court's summary judgment ruling, Paddock's request that portions of Plaintiffs' expert testimony and scientific testing be stricken is moot. Schwarz Pharma's Objections are overruled and Judge Graham's Order is adopted.

IV. CONCLUSION

Based upon the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Paddock Laboratories, Inc.'s Motion for Summary Judgment [Docket No. 175] is **GRANTED**;

2. Schwarz Pharma's Objections [Docket No. 208] are **OVERRULED**; and

3. Magistrate Judge Jeanne J. Graham's Order [Docket No. 202] is **ADOPTED**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

BY THE COURT:

s/Ann D. Montgomery
ANN D. MONTGOMERY
U.S. DISTRICT JUDGE

Dated: October 20, 2006.